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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	5

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/742,520	Abuljayadel
Examiner	**Art Unit**
F. Pierre VanderVegt	1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Dec 20, 2000*

2a) ☐ This action is **FINAL**. 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *47-65* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) X Claim(s) *47-65* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) X Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) X All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. X Certified copies of the priority documents have been received in Application No. *08/594,164*.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) X Information Disclosure Statement(s) (PTO-1449) Paper No(s): *3,4*

18) ☐ Interview Summary (PTO-413) Paper No(s).

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other

DETAILED ACTION

This application is a divisional of application serial number 09/521,700, which is a divisional of application serial number 08/594,164.

Claims 1-46 have been canceled.

New claims 47-65 have been added and are currently pending in this application.

Claim Rejections - 35 U.S.C. § 112

1. Claims 47-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for increasing the relative number of CD45low cells by incubating a population with an antibody to DR β-chain, does not reasonably provide enablement for increasing CD45low cells by other methods or isolating non-human CD45 low cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a method of increasing the number of CD45low cells in a population of cells which includes CD45 positive committed hematopoietic cells. The instant specification is not enabling for the claimed invention. The sole disclosure in the instant specification for an increase in the relative number of CD45low cells is found at pages 28-29. There the specification discloses that CD45 is found on all human leukocytes (page 28, line 1 in particular) and represents a family of protein tyrosine phosphatases and helps regulate cell growth and differentiation (page 28, lines 12-14 in particular). The specification goes on to disclose that "engagement of the β-chain of the DR antigens...affects the level of CD45 antigen on B-lymphocytes" (page 28, lines 16-18 in particular) and that "[o]n treatment the relative number of CD45 low cells increased significantly and so did the number of cells co-expressing the CD45 and CD14 antigens" (page 28, lines 25-27 in particular). The method of "engagement" or "treatment" is disclosed in the instant specification at pages 19-20 and consists of binding the homologous region of the β-chain of the HLA-DR antigen with a monoclonal antibody and mixed for up to 24 hours (page 19, lines 14-19 in particular). Other than this method of binding the DR β-chain with antibody, the instant specification does not teach any other method for the increase of the relative

number of CD45low cells in a mixed population. Based upon the lack of guidance in the instant specification and lack of working examples, it would require an undue level of experimentation on the part of one of ordinary skill in the art at the time the invention was made to practice the claimed invention, effecting a relative increase in the number of CD45low cells, commensurate with the scope of the claims. Further, the specification discloses only the engagement or treatment of the cells with antibodies to HLA DR β-chain. HLA is well known in the art to be the designation of the group of antigens which comprise the major histocompatibility complex (MHC) in the human. The designation HLA is not used for any other species. The specification does not teach the binding of MHC antigens in other species to cause a similar relative CD45low increase, nor does the specification disclose any species equivalents of HLA DR β-chain.

In view of the experimentation necessary, the limited working examples, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

2. Claims 47-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of claims 47-65, drawn to a method of increasing the number of CD45low cells in a population of cells which includes CD45 positive committed hematopoietic cells, includes in scope said increase in non-human cell populations and any method of engaging hematopoietically committed cells. *Vas-Cath Inc. v. Mahurkar* ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). It is respectfully submitted that the disclosure of the instant specification, in fact, clearly encompasses only the engaging or treatment

of cells with antibodies to HLA DR β-chain, as evidenced by the specification as originally filed at pages 19-20 and 28-29. Further, since HLA antigens are present only in humans, there is no evidence that the practice of the claimed invention was conceived in any other species. Accordingly, there is evidence that the full scope of the claimed invention was not in Applicant's possession as of the filing date sought.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

3. Claims 47-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 47 is ambiguous and unclear in that it is not readily apparent from the reading of the claim, including in light of pages 28-29 of the specification, which cells are the committed cells, the desired CD45low cells of the claim or the alternative CD45 high cells, IE, is the method one of positive or negative selection of cells? Clarification in the claim is needed.

Claim 47 recites the limitation "the relative number of CD45 negative cells increases" in lines 5-6. There is insufficient antecedent basis for this limitation in the claim. The preamble of the claim in line 1 recites only "increasing the relative number of CD45low cells."

Claim 53 recites the limitation "the CD3 negative DR negative cells" in line 1. There is no antecedent basis for this limitation in the claim. Base claim 1 recites only "increasing the relative number of CD45low cells."

Conclusion

4. Reference "AR" on form PTO-1449 filed 3/2/01 was lined through because the cited pages are within the reference cited as "AI" and did not need to be again considered.

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

6. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
May 21, 2001